

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMICUS THERAPEUTICS US, LLC AND
AMICUS THERAPEUTICS, INC.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.; and
TEVA PHARMACEUTICALS, INC,

Defendants.

C.A. No. 22-1461-CJB
ANDA CASE

Consolidated

**STIPULATION AND COVENANT NOT TO SUE
REGARDING U.S. PATENT NO. 12,109,205**

WHEREAS Plaintiffs Amicus Therapeutics US, LLC (“ATUS”) and Amicus Therapeutics, Inc. (“AT”) (collectively “Amicus”) and Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, “Aurobindo or “Defendants”), through their counsel, hereby stipulate and enter into the following covenant not to sue for purposes of streamlining issues for trial:

NOW THEREFORE:

1. AT represents and warrants that it owns U.S. Patent No. 12,109,205 (“the ’205 Patent”), titled “Methods of Treating Fabry Patients Having Renal Impairment.”
2. Aurobindo represents and warrants that Aurobindo submitted and holds Abbreviated New Drug Application (“ANDA”) No. 217786, seeking approval from the Food and Drug Administration to engage in the commercial manufacture, use, sale, or offer for sale of its proposed generic version of GALAFOLD migalastat 123mg free base capsules.
3. Amicus and its successors and assigns stipulate and covenant not to sue or otherwise assert patent infringement against Aurobindo, its successors, assigns, affiliates, parents,

subsidiaries, customers, manufacturers, distributors, importers, licensees, marketing partners or suppliers for any claims of the '205 Patent based on Aurobindo's filing of the ANDA No. 217786 or importing, making, using, selling, or offering for sale products that are the subject of and as described in ANDA No. 217786.

4. Aurobindo its successors and assigns stipulate and covenant not to sue or otherwise bring declaratory judgment proceedings against Amicus, its successors, assigns, affiliates, parents, or subsidiaries, for non-infringement, invalidity, or unenforceability of any claims of the '205 Patent based on Aurobindo's filing of the ANDA No. 217786 or importing, making, using, selling, or offering for sale products that are the subject of and as described in ANDA No. 217786.

Dated: January 7, 2025

BARNES & THORNBURG LLP

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*Attorney for Aurobindo Pharma Ltd. and
Aurobindo Pharma USA, Inc.*

IT IS SO ORDERED, DECREED, AND ADJUDGED this ____ day of _____,
2025.

The Honorable Christopher J. Burke
United States Magistrate Judge